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Ihre Zeichen und Nachrichten vom	Gesch.-Z.: Bitte bei Antwort angeben	Tel.-Durchwahl/Fax	Datum	Org.-Einheit/Ansprechpartner
01. November 2004		fone-2270 fax -2958	15.12.2004	Head of Department 3 & Head of ZEBET

Zebet Zentralstelle zur Erfassung und Bewertung von Ersatz- und Ergänzungsmethoden zum Tier-
 versuch im BfR, ☎+49-(0)1888-412-2270; Fax -2958; E-mail: zebet@bfr.bund.de

ICCVAM EXPERT PANEL REVIEW OF IN VITRO TEST METHODS FOR IDENTIFYING OCCULAR CORROSIVES AND SEVERE IRRITANTS

Public comment concerning the HET-CAM Background Review Document (BRD)

Dear Dr. Stokes,

as you know I served as an expert at the extended working group meeting organized by the ICCVAM Ocular Toxicity Working Group (OTWG) on April 19 and 20, 2004, in Bethesda, Maryland. Currently I am serving as an expert for the IRE (Isolated Rabbit Eye) test in the expert review panel of in vitro tests for identifying ocular corrosives and severe irritants.

To support the ICCVAM Expert Panel Review I have submitted several data sets for review that were generated in a national German validation study of the HET-CAM test as head of ZEBET, the National German Center for Documentation and Evaluation of Alternatives to Testing in Animals, at the BfR, the National Institute for Risk Assessment. In order to avoid any conflicts of interest and due to time constraints in my new position as head of the department "scientific services" of the BfR, I have so far not commented on the HET-CAM BRD, that you have circulated for public comment on behalf of NICEATM on November 1, 2004.

However, after studying the HET-CAM BRD and taking into account my responsibility as principal scientist and author of the documents that I submitted to NICEATM and also the substantial funding of the validation study by the Federal German Minister for Research and Technology (BMBF), I want to comment on the HET-CAM BRD, since some of the informa-

tion that I provided is not documented appropriately in the HET-CAM BRD. In particular the extensive biostatistical evaluation of the study (Spielmann et al., 1996), which was conducted in a joint national biostatistical project that was funded by the Federal German Minister for Research and Technology (BMBF), has not been taken into account although I have on several occasions offered to support the experts at NICESATM.

For the reasons given, I want to ask you to provide the experts of NICEATM and the expert panel of the HET-CAM BRD with the enclosed information, which may help to better evaluate the HET-CAM documents that I have submitted.

If you need further information, please do not hesitate to contact me.

With the best regards
Sincerely

A handwritten signature in black ink, which appears to read 'H. Spielmann', is positioned below the closing text.

Dr. med. Horst Spielmann
Direktor und Professor
Head of Dept. 3 "Scientific Services"
and Head of ZEBET

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